Updated interim phase IIa data demonstrate that the combination of simeprevir, odalasvir and AL-335 has a high level of efficacy in HCV patients

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that updated interim data from a phase IIa study being conducted by Alios BioPharma Inc., part of the Janssen Pharmaceutical Companies (Janssen), were presented on September 23rd at the European Association for the Study of the Liver (EASL) Special Conference in Paris, France.

The updated results, which include expanded safety and efficacy data, were presented in the ePoster entitled "Short duration treatment with AL-335 and odalasvir (ODV), with or without simeprevir (SMV), in treatment naïve patients with hepatitis C virus (HCV) genotype (GT) 1 infection." The data show that 100 percent of patients receiving treatment for as short as six weeks with a triple combination of once-daily (QD) simeprevir 75mg and AL-335 800mg with 50mg every other day (QOD) of ODV achieved a sustained viral response 12 weeks after the completion of treatment (SVR12) as shown in the table below.

Cohort #	Simeprevir dose (mg)	Odalasvir dose (mg)	AL-335 dose (mg)	Treatment Duration (weeks)	Number (%) with SVR12 or SVR24
1	100 QD	50 QD	400 QD	8	20/20 (100%), SVR24
2	--	50 QOD	800 QD	8	18/20 (90%), SVR12
3	75 QD	50 QOD	800 QD	8	20/20 (100%), SVR12
4	75 QD	50 QOD	800 QD	6	20/20 (100%), SVR12

QD: every day; QOD: every other day; SVR: sustained virologic response.

This study was designed to determine the safety, pharmacokinetics, and efficacy of different dosing regimens containing ODV and AL-335, with or without SMV, in treatment naïve patients with GT1 HCV infection for treatment durations of eight or six weeks. In all of these cohorts, the dosing regimens were generally well-tolerated. The majority of adverse events (AEs) were mild and the most commonly reported events were headache, fatigue, and upper respiratory tract infection. As previously reported in the abstract, there was one serious adverse event (SAE) in cohort 1 that resulted in premature discontinuation of all study drugs. This consisted of a Mobitz Type 1 2nd degree atrioventricular block and was deemed probably related to ODV and possibly related to AL-335 and simeprevir. The event was not associated with clinical or echocardiographic abnormalities, did not require any therapeutic intervention, resolved following treatment discontinuation, and the patient went on to achieve SVR24. No clinically significant laboratory, echocardiography, or ECG abnormalities (except the SAE) were reported.

Selection of the triple combination for further development

Based on the interim data from this study, the triple combination of simeprevir 75mg QD, odalasvir 25mg QD and AL-335 400mg QD has been selected for further development. The development program for the triple combination will include a multi-center, randomized, open-label study that will enroll treatment-naive and

treatment-experienced non-cirrhotic patients chronically infected with hepatitis C virus genotypes 1, 2, 4, 5, and 6. In addition, the ongoing phase IIa study is assessing the triple combination in patients with or without compensated cirrhosis, and with HCV genotype 3 infection.

Further information on these studies is available at www.clinicaltrials.gov with the reference numbers NCT02569710 and NCT02765490

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Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 17.50 CET on 23rd September 2016.

About Medivir

Medivir is a research based pharmaceutical company with a research focus on oncology and infectious diseases. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to develop innovative pharmaceuticals that meet great unmet medical need. Our commercial organization provides a portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.